IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS

Hegedus et al.

SERIAL NO.

10/802,528

FILING DATE

March 17, 2004

PATENT NO.

7,501,455 B2

ISSUE DATE

March 10, 2009

FOR

PHARMACEUTICAL COMPOSITIONS CONTAINING

PLASMA PROTEIN

EXAMINER

Wegert

GROUP ART UNIT:

1647

MAIL STOP: PETITION

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Cindy Cohen

PETITION UNDER 37 C.F.R. §§1.78(a)(3) AND 1.55(c) TO ACCEPT LATE PRIORITY CLAIM

Sir:

This Petition is being filed to request acceptance of the accompanying Request for Certificate of Correction to correct a late claim for priority. The Request seeks to add the following priority claim to the specification of U.S. Patent No. 7,501,455 B2 (the present patent), after the title, and to add corresponding priority information to the face of the present patent:

This application is a continuation of U.S. Patent Application Serial No. 09/299,562, filed April 27, 1999, now U.S. Patent No. 6,743,826, which is a continuation of PCT International Application No. PCT/HU98/00086, filed September 17, 1998, which designated the United States and on which priority is claimed under 35 U.S.C. §120. Priority of Application

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No. HU P97 01554 filed in Hungary September 18, 1997 is claimed under 35 U.S.C. §119.

Background

U.S. Patent Application Serial No. 10/802,528 (the present application), which matured into U.S. Patent No. 7,501,455 B2 (the present patent), was filed with a Transmittal Sheet that attempted to claim priority as a continuation from a prior copending U.S. non-provisional application, as a continuation from a PCT application, and from a Hungarian patent application. A copy of the Transmittal Sheet is enclosed as Exhibit A. See page 2 of Exhibit A, where the following is stated:

This application is a continuation of U.S. Application Serial No. 09/299,562, filed April 27, 1999, which is a continuation of PCT Application No. PCT/HU98/00086, filed on September 17, 1998, which designated the United States, which in turn claims priority of under 35 U.S.C. §119 of Hungarian Patent Application Serial No. HU P 97 01554, filed September 18, 1997, the entire contents of all of which are hereby incorporated by reference.

Due to an oversight, no Application Data Sheet was filed with the present application and the specification of the present application was not amended to insert the above-described priority claim. Accordingly the present patent issued without a priority claim.

The Petitioner submits that it is proper to add the above described priority claim to the present patent by Certificate of Correction. The reasons why it is proper to add this priority claim by Certificate of Correction are addressed separately below for each prior application listed in the priority claim.

Priority from U.S. Patent Application Serial No. 09/299,562 (the '562 application)

The '562 application is a prior U.S. non-provisional patent application. Thus, a claim for priority for the present application from the '562 application, if proper, would be made under 35 U.S.C. §120 and would therefore need to comply with 37 C.F.R. §1.78(a)(2)(iii), which states:

If the later-filed application is a nonprovisional application, the reference required by this paragraph must be included in an application data sheet (§

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1.76), or the specification must contain or be amended to contain such reference in the first sentence(s) following the title.

As discussed above, the present application failed to comply with 37 C.F.R. §1.78(a)(2)(iii) because no Application Data Sheet was filed and the specification was not amended to recite a claim for priority from the '562 application.

There are some circumstances where a failure to satisfy 37 C.F.R. §1.78(a)(2) with respect to a prior non-provisional application can be corrected by a Certificate of Correction. MPEP §1481.03(II)(B) states, in relevant part:

Under certain conditions as specified below, however, a Certificate of Correction can still be used, with respect to 35 U.S.C. 120 priority, to correct:

(A) the failure to make reference to a prior copending application pursuant to 37 CFR 1.78(a)(2); or

. . .

Where priority is based upon 35 U.S.C. 120 to a national application, the following conditions must be satisfied:

- (A) all requirements set forth in 37 CFR 1.78(a)(1) must have been met in the application which became the patent to be corrected;
- (B) it must be clear from the record of the patent and the parent application(s) that priority is appropriate (see MPEP § 201.11); and (C) a grantable petition to accept an unintentionally delayed claim for the benefit of a prior application must be filed, including a surcharge as set forth in 37 CFR 1.17(t), as required by 37 CFR 1.78(a)(3).

The failure to make reference to the '562 application pursuant to 37 C.F.R. §1.78(a)(2) during the prosecution of the present application may be corrected by Certificate of Correction because conditions (A), (B), and (C) above are met.

Condition A

Condition A states that the requirements set forth in 37 C.F.R. §1.78(a)(1) must have been met in the present application. 37 C.F.R. §1.78(a)(1) reads as follows:

(a)(1) A nonprovisional application or international application designating the United States of America may claim an invention disclosed in one or more prior-filed copending nonprovisional applications or international applications designating the United States of America. In order for an application to claim the benefit of a prior-filed copending

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nonprovisional application or international application designating the United States of America, each prior-filed application must name as an inventor at least one inventor named in the later-filed application and disclose the named inventor's invention claimed in at least one claim of the later-filed application in the manner provided by the first paragraph of 35 U.S.C. 112. In addition, each prior-filed application must be:

(i) An international application entitled to a filing date in accordance with

- (i) An international application entitled to a filing date in accordance with PCT Article 11 and designating the United States of America; or
- (ii) Entitled to a filing date as set forth in § 1.53(b) or § 1.53(d) and have paid therein the basic filing fee set forth in § 1.16 within the pendency of the application.

37 C.F.R. §1.78(a)(1) requires that there be at least one common inventor between the present application and the '562 application. This requirement is met because the inventorship of the present application and the inventorship of the '562 application are identical. See Exhibit B (copy of Declaration filed in the present application) and Exhibit C (copy of Declaration filed in the '562 application). The same inventors are listed in Exhibits B and C.

37 C.F.R. §1.78(a)(1) requires that the common inventor's invention claimed in the present application must have been disclosed in the '562 application in the manner provided by 35 U.S.C. §112. This requirement is met because the present application is a continuation of the '562 application and thus has the same disclosure as the '562 application. This can be verified by comparing the specification of the present patent (Exhibit D) to the specification of U.S. Patent No. 6,743,826 (Exhibit E), the patent that that issued from the '562 application. Since both the present patent and U.S. Patent No. 6,743,826 issued with the same inventorship, it must be that the United States Patent and Trademark Office determined that at least one of the inventions of at least one of the common inventors of the present patent is described in both patents in the manner provided by 35 U.S.C. §112.

37 C.F.R. §1.78(a)(1) requires that the '562 application must have been entitled to a filing date and have paid the basic filing fee. This requirement is met because the '562 application matured into U.S. Patent No. 6,743,826. See Exhibit E (copy of U.S. Patent No. 6,743,826).

Condition B

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Condition B states that it must be clear from the record of the present patent and the record of the '562 application that priority is appropriate. This condition is met because it is clear from the record of the present patent and the '562 application that the present patent meets all the requirements of 35 U.S.C. §120 for claiming priority from the '562 application. 35 U.S.C. §120 reads as follows:

An application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States, or as provided by section 363 of this title, which is filed by an inventor or inventors named in the previously filed application shall have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application. No application shall be entitled to the benefit of an earlier filed application under this section unless an amendment containing the specific reference to the earlier filed application is submitted at such time during the pendency of the application as required by the Director. The Director may consider the failure to submit such an amendment within that time period as a waiver of any benefit under this section. The Director may establish procedures, including the payment of a surcharge, to accept an unintentionally delayed submission of an amendment under this section.

The record of the present patent and the record of the '562 application indicate that the present patent and the '562 application were co-pending. See Exhibit D (copy of the present patent), which indicates that the present application was filed on March 17, 2004 and issued as the present patent on March 10, 2009. Exhibit E (copy of U.S. Patent No. 6,743,826; which issued from the '562 application) indicates that the '562 application was filed on April 27, 1999 and issued as U.S. Patent No. 6,743,826 on June 1, 2004. Thus, the present application and the '562 application were co-pending from March 17, 2004 to June 1, 2004.

The record of the present patent and the record of the '562 application indicate that the present patent and the '562 application have the same inventorship. See discussion above.

The record of the present patent and the record of the '562 application indicate that the requirement of 35 U.S.C. §120 that the invention of the present patent must have NY01 2041927 v1

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been disclosed in the '562 application in the manner provided by 35 U.S.C. §112 is met because, as discussed above, the present patent is a continuation of the '562 application and thus has the same disclosure as the '562 application and the inventorship of the present patent and the '562 application is the same.

Condition C

Condition C will be met upon the granting of this Petition.

Priority from International Patent Application No. PCT/ HU98/00086 (the PCT application)

The PCT application is an international patent application. Thus, a claim for priority for the present application as a continuation from the PCT application, if proper, would be made under 35 U.S.C. §120 and would therefore need to comply with 37 C.F.R. §1.78(a)(2)(iii). As discussed above, the present application failed to comply with 37 C.F.R. §1.78(a)(2)(iii).

There are some circumstances where a failure to satisfy 37 C.F.R. §1.78(a)(2) with respect to a prior international application can be corrected by a Certificate of Correction. MPEP §1481.03(II)(B) states:

Where 35 U.S.C. 120 and 365(c) priority based on an international application is to be asserted or corrected in a patent via a Certificate of Correction, the following conditions must be satisfied:

- (A) all requirements set forth in 37 CFR 1.78(a)(1) must have been met in the application which became the patent to be corrected;
- (B) it must be clear from the record of the patent and the parent application(s) that priority is appropriate (see MPEP § 201.11);
- (C) the patentee must submit together with the request for the certificate, copies of documentation showing designation of states and any other information needed to make it clear from the record that the 35 U.S.C. 120 priority is appropriate (see MPEP § 201.13(b) as to the requirements for 35 U.S.C. 120 priority based on an international application; and (D) a grantable petition to accept an unintentionally delayed claim for the

(D) a grantable petition to accept an unintentionally delayed claim for the benefit of a prior application must be filed, including a surcharge as set forth in 37 CFR 1.17(t), as required by 37 CFR 1.78(a)(3).

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The failure to make reference to the PCT application pursuant to 37 C.F.R. §1.78(a)(2) during the prosecution of the present application may be corrected by Certificate of Correction because conditions (A), (B), (C), (D) above are met.

Condition (A)

Condition (A) states that the requirements set forth in 37 C.F.R. §1.78(a)(1) must have been met in the present application. This is the same condition as Condition (A) discussed above in connection with priority from the '562 application. As discussed above, Condition (A) requires common inventorship, disclosure in the prior application according to 35 U.S.C. §112, and that the prior application have been accorded a filing date.

The present application and the PCT application have the same inventorship. Compare Exhibit B (Declaration of the present application) with the cover page of Exhibit F (copy of WO 1999013914, the publication of the PCT application).

Condition (B)

Condition (B) states it must be clear from the record of the present patent and the record of the PCT application that priority is appropriate. This condition is met because it is clear from the record of the present patent and the record of the PCT application that the present patent meets all the requirements of 35 U.S.C. §120 for claiming priority from the PCT application.

The present patent and the PCT application have the same inventorship. Compare Exhibit D (copy of the present patent) and Exhibit F (copy of the publication of the PCT application).

The present patent and the PCT application have the same disclosure since the present patent is a continuation of an application (the '562 application) that is itself a continuation of the PCT application. Compare the disclosures of Exhibit D (copy of the present patent) and Exhibit F (copy of the publication of the PCT application).

The PCT application was co-pending with the '562 application. As discussed above, the '562 application was pending from April 27, 1999 to June 4, 2004. The PCT

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application was filed on September 17, 1998 (see Exhibit F) and expired one year later (September 17, 1999). The PCT application and the '562 application were therefore copending from April 27, 1999 (the filing date of the '562 application) to September 17, 1999 (the expiration date of the PCT application). Thus, there is an unbroken chain of copendency between the present patent and the PCT application, with the '562 application providing the link in the chain that unites the present patent and the PCT application.

Condition (C)

Condition (C) requires the submission of copies of documentation showing the designation of states in the PCT application and any other documentation required to show that priority from the PCT application is appropriate under 35 U.S.C. §120.

Priority from the PCT application is appropriate under 35 U.S.C. §120 because:

- The U.S. was designated in the PCT application (see the cover page of Exhibit F (copy of the PCT application));
- As discussed above, the present application and the PCT application have the same inventorship; and
- As discussed above, the present application and the PCT application have the same disclosure.

Condition (D)

Condition (D) will be met upon the granting of this Petition.

Priority from Hungarian Patent Application No. HU P97 01554 (the Hungarian application)

Claims for priority from foreign patent applications are made under 35 U.S.C. §119 rather than 35 U.S.C. §120 and are <u>not</u> governed by 37 C.F.R. §1.78. Thus, the requirement of 37 C.F.R. §1.78(a)(2)(iii) that priority claims must be made either in a

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Application Data Sheet or in the first sentence of the specification after the title does not apply to priority claims to foreign patent applications. See MPEP §201.14(b):

For all applications, the claim to priority need be in no special form, and may be made by a person authorized to sign correspondence under 37 CFR1.33(b). No special language is required in making the claim for priority, and any expression which can be reasonably interpreted as claiming the benefit of the foreign application is accepted as the claim for priority. The claim for priority may appear in the oath or declaration, an application data sheet (37 CFR1.76), or the application transmittal letter with the recitation of the foreign application. See MPEP § 201.13, paragraph A.

Thus, the priority claim to Hungarian Patent Application No. HU P97 01554 (the Hungarian application) in the Transmittal Sheet for the present application (Exhibit A) was proper in form.

Furthermore, the requirement in 37 C.F.R. §1.63 that the oath or declaration must refer to the foreign priority application was also met (see Exhibit B).

There is a requirement stemming from 35 U.S.C. §119(b) that a certified copy of the foreign application be filed, or, if such a certified copy was filed in a parent application, the application claiming priority from the parent application must identify the parent application as containing the certified copy. See MPEP §201.14(b)(II):

Where the benefit of a foreign filing date based on a foreign application is claimed in a later filed application (i.e., continuation, continuation-in-part, division) or in a reissue application and a certified copy of the foreign application as filed, has been filed in a parent or related application, it is not necessary to file an additional certified copy in the later application. A reminder of this provision is found in form paragraph 2.20. The applicant when making such claim for priority may simply identify the application containing the certified copy. In such cases, the examiner should

It may be that this requirement was not met in the present application. A certified copy of the Hungarian application was not filed during the prosecution of the present NY01 2041927 v1 9

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application, although a certified copy of the Hungarian application was filed during the prosecution of the '562 application. The Applicants of the present application did not refer to this certified copy in the file of the '562 application, but the Examiner of the present application did. In the Notice of Allowance for the present application (Exhibit G), at page 4, the Examiner wrote:

3. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some* c) None of the:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. 09/299.562.

If the Examiner's reference to the certified copy in the file of the '562 application was not sufficient to perfect the priority claim from the Hungarian application, the Petitioners submit that correcting the priority claim from the Hungarian application by Certificate of Correction is proper for the following reasons.

A certified copy of the Hungarian application was filed during the prosecution of the '562 application and a proper claim for priority from the Hungarian application satisfying the requirements of 35 U.S.C. §119 (a)-(d) or (f) was made in the '562 application. The present patent is a continuation of the '562 application. As explained in MPEP §201.16, these considerations, plus satisfaction of the requirements of 37 C.F.R. §1.55(a) and the filing of a petition under 37 C.F.R. §1.55(c), are sufficient to allow the perfection of the priority claim from the Hungarian application by Certificate of Correction. MPEP §201.16 states, in relevant part:

The failure to perfect a claim to foreign priority benefit prior to issuance of the patent may be cured by filing a reissue application. *Brenner v. State of Israel*, 400 F.2d 789, 158 USPQ 584 (D.C. Cir. 1968).

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However, under certain conditions, this failure may also be cured by filing a certificate of correction request under 35 U.S.C. 255 and 37 CFR 1.323. For example, in the case of *In re Van Esdonk*, 187 USPQ 671 (Comm'r Pat. 1975), the Commissioner granted a request to issue a certificate of correction in order to perfect a claim to foreign priority benefits. In that case, a claim to foreign priority benefits had not been filed in the application prior to issuance of the patent. However, the application was a continuation of an earlier application in which the requirements of 35 U.S.C. 119(a)-(d) or (f) had been satisfied. Accordingly, the Commissioner held that the "applicants' perfection of a priority claim under 35 U.S.C. 119 in the parent application will satisfy the statute with respect to their continuation application."

. . .

In summary, a certificate of correction under 35 U.S.C. 255 and 37 CFR 1.323 may be requested and issued in order to perfect a claim for foreign priority benefit in a patented continuing application if the requirements of 35 U.S.C. 119(a)-(d) or (f) had been satisfied in the parent application prior to issuance of the patent and the requirements of 37 CFR 1.55(a) are met. Furthermore, if the continuing application (other than a design application), which issued as a patent, was filed on or after November 29, 2000 **, in addition to the filing of a certificate of correction request, patentee must also file a petition for an unintentionally delayed foreign priority claim under 37 CFR 1.55(c).

All of the requirements of 35 U.S.C. §119 (a)-(d) or (f) were met in the '562 application. This was acknowledged by the Examiner in the Notice of Allowance (Exhibit H) for the '562 application, at page 4:

4. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some* c) None of the:
1. Certified copies of the priority documents have been received.

The relevant part of 37 C.F.R. §1.55(a) reads as follows:

In an original application filed under 35 U.S.C. 111(a), the claim for priority must be presented during the pendency of the application, and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior foreign

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application. This time period is not extendable. The claim must identify the foreign application for which priority is claimed ...

As discussed above, a claim for priority from the Hungarian application that was proper in form was made in the present application in the Transmittal Sheet (Exhibit A). Since the Transmittal Sheet was filed along with the application papers for the present application, this priority claim met the timeliness requirement of 37 C.F.R. §1.55(a). The priority claim in the Transmittal Sheet indentified the Hungarian application by specifying the Hungarian application's country, application number, and filing date, thus meeting the requirement of 37 C.F.R. §1.55(a) that the foreign application be "identified."

37 C.F.R. §1.55(c) states that a petition to accept an unintentionally delayed foreign priority claim must contain:

- (1) The claim under 35 U.S.C. 119(a)-(d) or 365(a) and this section to the prior foreign application, unless previously submitted;
 - (2) The surcharge set forth in § 1.17(t); and
- (3) A statement that the entire delay between the date the claim was due under paragraph (a)(1) of this section and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional.

These requirements are met by the present Petition (the request to pay the required fee and the statement re unintentional delay appear below).

Statement re unintentional delay

The undersigned certifies that the entire period of delay between the date the priority claims that are the subject of this Petition were due and the date of this Petition was unintentional.

Statement re required fees

Please charge the required fee for this Petition, estimated to be \$1,410, to Kenyon & Kenyon's Deposit Account No. 11-0600.

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All of the necessary requirements for the granting of this Petition being satisfied, it is respectfully requested that this Petition be granted and that the accompanying Certificate of Correction for U.S. Patent No. 7,501,455 be accepted.

Dated: November 22, 2010

By: /Joseph A. Coppola/ Joseph A. Coppola Registration No. 38,413

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